## Summary Of Safety And Effectiveness: NOV 13 2000

This safety and effectiveness summary for the Micron Precision Engineering AMT Spinal™ System is provided as required per Section 513(i)(3) of the Food, Drug, and Cosmetic Act.

1. **Submitter:**
   Micron Precision Engineering Inc.
   21051 Superior Street
   Chatsworth, CA 91311

2. **Mailing Address:**
   939 Evening Shade Drive
   San Pedro, CA 90731

3. **Contact Person:**
   Mr. Frank E. Bailly
   Official Correspondent
   Telephone: (310) 831-1873
   Fax: (818) 897-5799

4. **Trade Name:** AMT Spinal™ System
   **Common Name:** Hook, rod, and thorocolumbar screw spinal fixation system (KWP)
   Pedicle screw fixation system (MNH)
   **Classification Name:** Appliance, Fixation, Spinal Interlaminal (KWP)
   Orthosis, Spondylolisthesis Spinal Fixation (MNH)
   **FDA Product Code:** 87KWP
   87MNH

5. **Predicate or legally marketed devices which are substantially equivalent:**
   - **Contour™ Spinal System** – Ortho Development
   - **TSRH®** – Sofamor Danek
   - **ISOLA® Miami** – DePuy Acromed
   - **MOSS® Miami** – DePuy Acromed
   - **Universal** – Synthes

6. **Description of the device:**

   The AMT Spinal™ System is designed for use as a construct system and consists of set screws, hex nuts, hooks, rods, screws, and cross link which can be variously assembled to provide immobilization of the thoracic, lumbar, and lumbosacral spine. The system is composed of the following components: right hand set screw, left hand hex nut, pedicle screw, rod, cross link, and connecting hook. All components are made from Wrought Titanium 6Al4V ELI Alloy (ASTM F-136).

   Materials: All components are made from Wrought Titanium 6Al4V ELI Alloy (ASTM F-136).

   Function: The system functions to assist in arthrodesis or fusion of the thoracic, lumbar and lumbosacral spine.

**7. Intended Use:**

When used as a pedicle screw fixation system (MNH) The AMT Spinal™ System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion mass.

Use of a hook, rod, and ileo-sacral screw fixation system (KWP) T1-S1, the Lumbar Hook Pedicle Screw Construct of the AMT Spinal™ System, will assist in arthrodesis or fusion of the thoracic, lumbar and lumbosacral spine. The indications for use are:

- Spondylolisthesis;
- Fracture;
- Spinal Stenosis;
- Deformities (scoliosis, kyphosis, lordosis);
- Pseudarthrosis
- Tumor
- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Revision of previously failed fusion surgery

The hooks are to be used for fixation to include the first thoracic vertebra down to the sacrum. The pedicle screws are used for pedicle fixation only.

**8. Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

There are no significant differences between the Micron Precision Engineering AMT Spinal™ System and the systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2000

Mr. Frank E. Bailey
Official Correspondent
Micron Precision Engineering, Inc.
939 Evening Shade Drive
San Pedro, California 90731

Re: K002059
Trade Name: AMT™ Spinal System
Regulatory Class: II
Product Code: KWP and MNH
Dated: September 1, 2000
Received: September 8, 2000

Dear Mr. Bailey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K002059

## Device Name: AMT Spinal™ System

## Indications for Use

When used as a pedicle screw fixation system (MNH) The AMT Spinal™ System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion mass.

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**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark N. Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002059

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)